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(71) Applicant (for all designated States except US): **BORMI-OLI ROCCO & FIGLIO S.P.A.** [IT/IT]; Via San Leonardo, 41, I-43100 Parma (IT).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **MORINI, Emilio** [IT/IT]; Via A. Moro, 35, I-43052 Colomo (IT).

(74) Agent: **NERI, Luciano**; Bugnion S.p.A., Via Emilia Est, no. 25, I-41100 Modena (IT).

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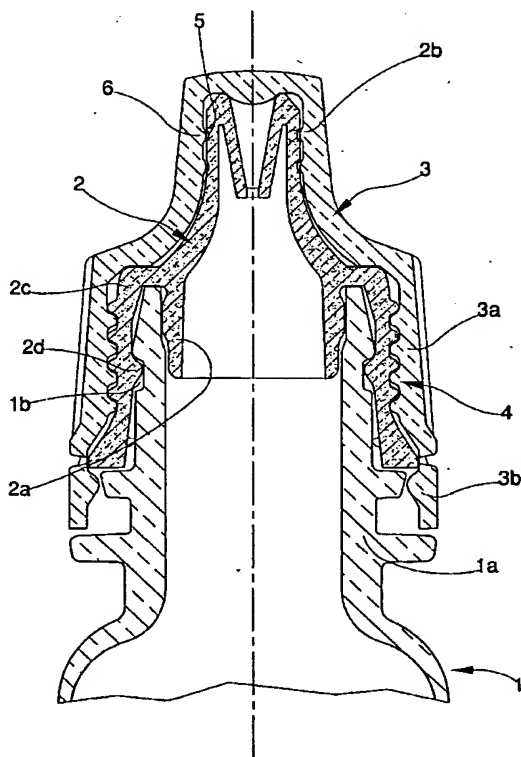
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(54) Title: A PROCESS FOR STERILE PACKAGING OF CONTAINERS WITH DROP-DISPENSERS, AND MEANS FOR ACTUATING THE PROCESS



(57) Abstract: The process includes a stage of sterilisation of the flagon, the drop-dispenser and the closure cap making up the container, which is preceded by a stage in which the cap and the drop-dispenser are removably anchored together. In a subsequent stage the flagon and the drop-dispenser-cap group are placed in an aseptic environment, and the flagon is filled before the pre-assembled drop-dispenser-cap group is inserted on the flagon. The means for actuating the above process comprise a flagon (1), a drop-dispenser (2) which is pressure-inserted in the flagon (1) and a closure cap (3) which is screwed onto the drop-dispenser before the drop-dispenser (2) is inserted on the flagon (1).

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### Description

## A Process for Sterile Packaging of Containers with Drop-Dispensers, and Means for Actuating the Process.

### Technical Field

The invention relates to a process for sterile packing of containers with drop dispensers and means for actuating the process.

### Background Art

The prior art teaches containers with drop-counting dispensers closed by caps, often having a security strip, which containers must be packaged in sterile surroundings given the nature of their contents. These containers are used, for example, in the pharmaceutical field, and in particular in the field of ophthalmology, for containing eye-drops, for sterile cleaning liquids, and the like.

Generally these containers comprise a flagon, made of glass or a plastic material, which is provided with a drop dispenser and closed by a cap made of plastic. The invention relates in particular to the latter type of container, with drop-dispenser and plastic cap.

At present the sterile packaging of these containers which obviously takes place in sterile surroundings, is performed in the following way.

The packaging companies, which are generally pharmaceutical industries, receive the various pieces making up the container in closed packages containing a high number of units; in particular, packages containing the flagons, the drop-dispensers and the caps are separately delivered.

The packages arrive at the pharmaceutical packagers with their internal parts already sterile, or they can be sterilised after arriving; the sterilisation thereof is

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done, with the packages closed, by gamma ray bombardment which sterilises the insides of the packages without any need to open them.

Using various lines and systems, of known type, these packages are introduced into a sterile environment and are opened while there, so that the sterility thereof is not compromised. The various sterile parts which exit are sent on to machines, located in the sterile environment, which position and predispose the various pieces for the filling and closing stages of the containers.

During this packaging stage, which as has been mentioned is done in a sterile environment and in general using continuous automatic machines, the flagon is filled with the product in a work station; in a following work station, the drop-dispenser is inserted on the flagon by press-fit; and in a further work station the flagon-drop dispenser assembly is completed by screwing on the cap, at which point the container exits the sterile environment and is ready to be put up for sale. This packaging process involves considerable expense, primarily for sterilisation of the parts of the container; gamma ray sterilisation includes costs that are calculated in terms of "occupied volume", i.e. the number of objects to be sterilised, which, in the described process, is a very high number even though the volume consists mostly of empty space, being the inside of the containers, the drop-dispensers and the closure caps which are hollow elements. Secondly, the high costs are due to the presence, internally of the sterile machines where the packaging takes place, of a high number of infeeding lines of the single components and a large number of work stations, which, apart from the cost of these specific lines and stations, lead to the need to keep a fairly large space under sterile conditions.

A further drawback in the known processes is the difficulty of regulating the torque in the cap-dispenser coupling.

The main aim of the present invention is to provide a process for sterile

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packaging of containers having drop-dispensing mechanisms, and the means for realising the process, which process and means reduce the drawbacks in the prior art, and in particular reduce the costs and wastage during the packaging process. An advantage of the invention is that container packaging times are reduced. A further advantage of the invention is that containers are obtained which are safer and easier for a consumer to use.

These aims and advantages are achieved by the invention, as it is characterised in the appended claims.

#### **Disclosure of Invention**

Further characteristics and advantages of the present invention will better emerge from the detailed description that follows of a possible actuation of the process, and a possible embodiment of the means for realising the process, illustrated purely by way of non-limiting example in the accompanying figure 1, which shows a section in vertical elevation of a flagon group, drop-dispenser and cap which make up the means for actuating the process of the invention.

The sterile packaging process is applied on containers used in particular in the pharmaceutical field for containing products such as medicinal drops, sterile cleaning liquids and the like, which containers comprise a flagon 1, made preferably of a plastic material, on which after filling with the product they are destined to contain, a drop-dispenser 2 and a closure cap 3 are to be fitted, the cap 3 closing the package but which can be removed to enable use of the product, and replaced to close the flagon before further use; both the drop-dispenser 2 and the cap 3 are made of a plastic material, and preferably by injection moulding.

The process includes, as with known processes, a sterilisation stage of the flagon, the drop-dispenser and the closure cap.

While the sterilisation of the flagon is done using known processes, for sterilising the drop-dispenser and the cap the process of the invention includes a preparation

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stage of removably anchoring the closure cap on the drop-dispenser; this anchoring stage is done under conditions of perfect cleanliness but not necessarily sterility, generally by the manufacturer of the drop-dispenser and the cap; during this stage the cap and the drop-dispenser are solidly constrained to one another and a pre-assembled group is obtained, which is already configured to be directly connected to the flagon. This anchoring stage, however, produces a connection between the drop-dispenser and the cap which can be resolved at moment of use of the package; for this purpose the anchoring stage of the cap on the drop-dispenser is achieved by a threaded coupling between an outside of the drop-dispenser and an inside of the cap, which easily enables, at moment of use, the anchored state between the drop-dispenser and the cap to be removed and replaced, i.e. the container can easily be opened and closed.

Once assembled, the drop-dispenser-cap groups are packed in a packaging, which contains a considerable number of units, which is sent on to a successive stage of sterilisation of the pre-assembled groups; this sterilisation stage is performed, with the packagings closed, by bombardment of gamma rays which, in a known process, sterilise the inside of the packaging and the contents thereof with no need for opening the packaging.

With respect to known processes, this stage of sterilisation, the economic cost of which depends on the volume of the packaging, is much less expensive because the volume occupied by the drop-dispenser-cap groups is much smaller (with the drop-dispenser-cap groups proposed for actuating the process of the invention, as shall be seen herein below, the volume is about half) than the totality of the volumes occupied by the drop-dispenser and cap when considered separately; in other words, with the sterilisation of the volume represented, in known processes, by the packaging containing the caps, sterilisation can be performed of both the cap and the drop-dispenser.

This stage of sterilisation can be performed by the packaging company or, as frequently occurs, by an external company, which sends the packaging company the packages containing the drop-dispenser-cap groups already sterilised.

The drop-dispenser-cap groups are then placed in an aseptic environment represented by the plant performing the filling and closing of the packages; the flagons are also placed in the aseptic environment. The flagons are then filled in this aseptic environment, following known processes.

Once the flagon is filled the pre-assembled drop-dispenser-cap group is inserted, so that in a single operation at a single work-station the package is provided with the drop-dispenser and the cap destined to close the container.

The insertion stage of the pre-assembled drop-dispenser-cap group is performed by a simple pressure-insertion of the drop-dispenser-cap group on the neck of the flagon. This stage is much simpler and more reliable than known processes, which include a pressure insertion of the drop-dispenser on the flagon followed by the screwing-on of the cap on the neck of the flagon. The screwing-on of the cap is indeed rather a delicate operation and must be done most carefully in order not to subject the cap to erroneous torques which might lead to an imperfect insertion of the cap, or even a breakage of the cap. In the process of the invention, the screw-on stage, which is generally done after the realisation of the drop dispenser and the cap, is made especially easy because the screw-coupling is effected partly on the cap and partly on the drop-dispenser, which are both obtainable by injection moulding and thus with a very high forming precision: also, the assembly of the drop-dispenser-cap group is performed in much easier conditions, as although the realisation and manipulation of the various components is always done in perfectly clean conditions (hygienic ambience) the assembly thereof does not necessarily have to be done in a sterile environment. The above-described process also offers considerable advantages for transport

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and storage of the components of the package (the overall shipping volume of the drop-dispenser and the caps is halved). Control is also easier, as only one drop dispenser-cap group control is needed instead of the two required when the components are separate.

To actuate the above-described process means are used which comprise a container which in turn comprises a flagon 1, of which only the upper part is shown in the figure of the drawing, which flagon 1 is destined to contain the product to be packaged; an annular end 2a of a drop-dispenser 2 is press-fitted on the mouth 1a of the flagon 1, the drop-dispenser 2 being superiorly provided with an appendix 2b which doses the contents and which projects externally of the flagon 1 when the drop-dispenser is inserted in the mouth 1a. The drop-dispenser comprises a skirt 2c which is arranged externally of and concentrically to the annular end 2a. An annular cavity is defined between the skirt 2c and the end 2a, in which cavity the mouth 1a of the flagon is jointed when the drop-dispenser 2 is press-inserted on the flagon 1. To guarantee a solid joint of the drop-dispenser 2 on the flagon 1, there is an annular relief 2d internally on the skirt 2c, which lodges in a corresponding annular cavity 1b on the mouth of the flagon 1.

The means for realising the process further comprise a closure cap 3 having the function of closing the container and enabling it to be re-opened, so that the product in the container can be dosed by the drop-dispenser, and then closed. The cap 3 comprises a bell-shaped zone 3a which covers the skirt 2c of the drop-dispenser 2, and imitates the shape thereof, when the cap 3 is placed on the container to close it. Preferably the cap 3 also comprises a security strip arranged inferiorly of the cap and connected thereto, in a known way, by easy-break ribs. The strip is to evidence when a container has been opened. Also included are means for fastening which enable the cap 3 to be fastened removably to the drop-dispenser 2. The means for fastening comprise a screw-coupling 4 which is partly

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made on the external surface of the skirt 2c of the drop-dispenser 2 and partly on the internal surface of the bell 3a of the cap 3.

The screw-coupling 4 enables an easy and efficacious coupling between the drop-dispenser and the cap, usable for realising the previously-described process; also, thanks to the conformation of the drop-dispenser and the cap, and by means of the said coupling, a drop-dispenser-cap group is obtained which exhibits a volume equal to that of the cap alone, inasmuch as once the coupling is achieved the drop-dispenser is entirely contained inside the cap.

Preferably the appendix 2b for dosing on the drop-dispenser comprises, on an external surface thereof, one or two (as shown in the figure) annular cavities 5, in each of which, when the cap 3 is connected to the drop-dispenser 2, an annular relief 6 is inserted which annular relief 6 is made on the internal surface of the cap 3. This guarantees an excellent seal of the closed container.

The flagon 1, the drop-dispenser and the cap described define together means for actuating the process of the invention in a way which is easy and rapid. The process could however be actuated with different drop-dispensers and caps from those described, such as ones using a press-fitting, or having seal rings instead of the described annular cavities 5 and the annular reliefs 6; or even having different systems for identifying when the container has been first opened.



**Claims.**

1). A process for sterile packaging of containers with drop-dispensers, comprising stages of: sterilisation of components of the container comprising a flagon, a drop-dispenser and a closure cap; introduction of the components into an aseptic environment; filling of the flagon in the aseptic environment, insertion of the drop-dispenser on the flagon and closure of the flagon with the closure cap; wherein the process comprises a removable anchoring stage of the closure cap on the drop-dispenser, performed in non-sterile conditions, in order solidly and removably to constrain the cap to the drop-dispenser and to obtain a pre-assembled group comprising the drop-dispenser and the cap which is configured to be directly connected to the flagon; the process further comprises a stage of sterilisation of the pre-assembled drop-dispenser-cap group; the process further comprises an introduction stage of the drop-dispenser-cap group into an aseptic environment; the process further comprises an insertion stage of the pre-assembled drop-dispenser-cap group onto the flagon.

2). The process of claim 1, wherein the anchoring stage of the closure cap onto the drop-dispenser is performed by means of a screw-coupling between an outside of the drop-dispenser and an inside of the cap.

3). The process of claim 1, wherein the stage of insertion of the pre-assembled drop-dispenser-cap group on the flagon is performed by pressure-insertion of the drop-dispenser-cap group on the mouth of the flagon.

4). The process of claim 1, wherein the stage of sterilisation of the pre-assembled

drop-dispenser-cap group is performed by inserting a plurality of the pre-assembled drop-dispenser-cap groups into a closed package and treating the closed package with gamma rays.

5). Means for actuating the process of claim 1, which means comprise a container which in turn comprises a flagon (1) for containing a product to be packaged, provided with a drop-dispenser (2) and closed by a closure cap (3), wherein: the flagon (1) is provided with a mouth (1a) in which an annular end (2a) of the drop-dispenser (2) is pressure-inserted; the drop-dispenser comprises an appendix (2b) for dosing the product, which appendix (2b) projects externally of the flagon (1), and a skirt (2c), external of and concentric to the annular end (2a), which skirt (2c) together with the annular end (2a) defines an annular cavity in which the mouth (1a) of the flagon (1) joints; means for fastening being located on an external surface of the skirt (2c) for removably fastening the closure cap (3) to the drop-dispenser (2).

6). The means of claim 5, wherein: the cap (3) comprises a bell-shaped zone (3a) which covers the skirt (2c) of the drop-dispenser; the means for fastening comprise a screw-coupling (4) made partly on an external surface of the skirt (2c) and partly on an internal surface of the bell (3a).

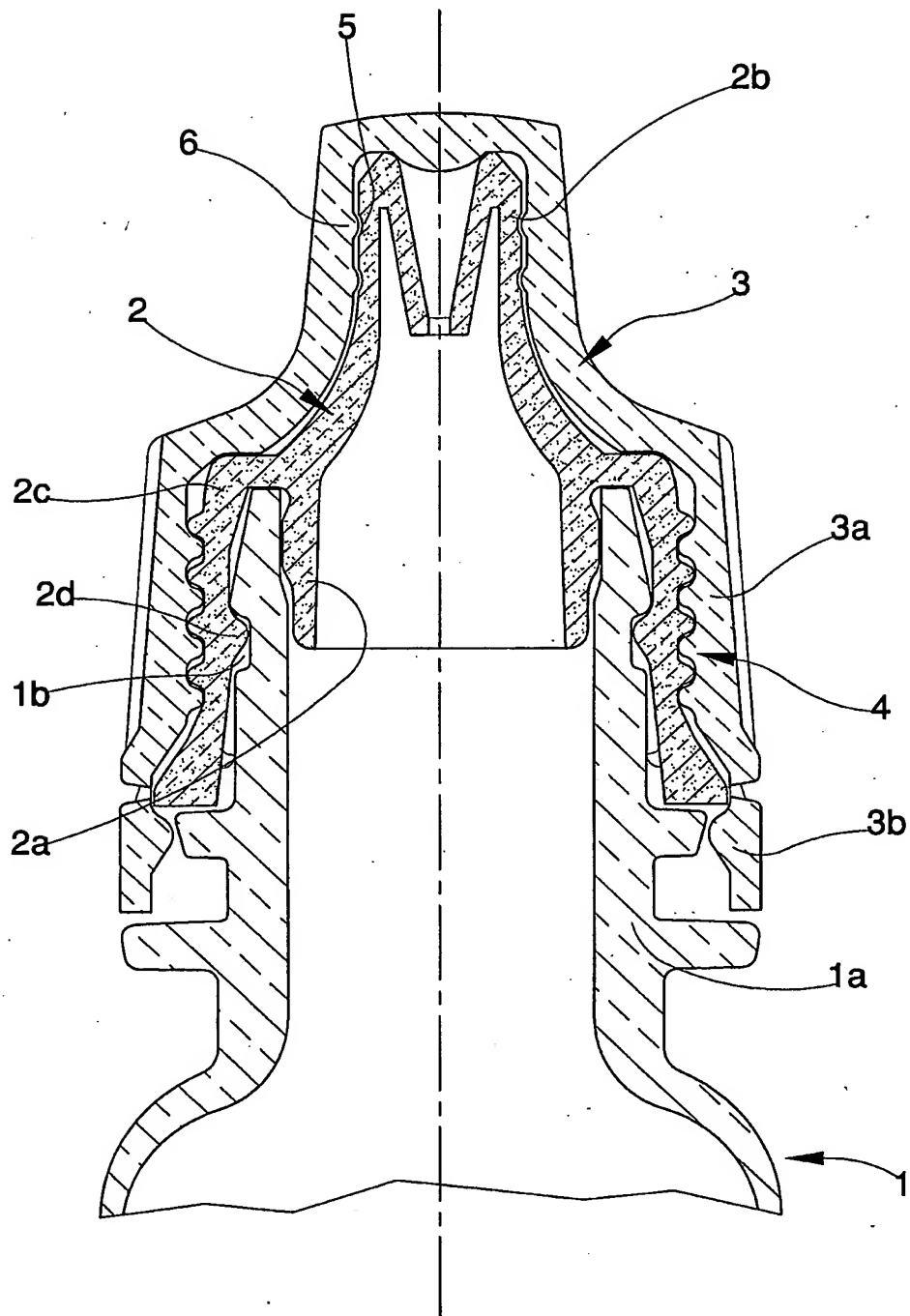
7). The means of claim 6, wherein the cap (3) comprises an annular security strip (3b) connected to the bell-shaped zone (3a) by easy-break ribs.

8). The means of claim 5, wherein the appendix (2b) for dosing of the drop-dispenser (2) comprises, on an external surface thereof, at least an annular cavity (5) in which an annular relief (6) is inserted when the cap (3) is connected to the

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drop-dispenser (2); the annular relief (6) being made on an internal surface of the cap (3).

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**Fig. 1**